10-3402

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

NORFOLK COUNTY RETIREMENT SYSTEM, STATE-BOSTON RETIREMENT SYSTEM, PUBLIC PENSION FUND GROUP,

Plaintiffs-Appellants,

JOSEPH MAS, HERMAN UNVERICHT,

Consolidated Appellants,

—v.—

KV PHARMACEUTICAL COMPANY, MARC S. HERMELIN, DAVID A. VAN VLIET, RITA E. BLESER,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI (ST. LOUIS)

BRIEF OF DEFENDANTS-APPELLEES KV PHARMACEUTICAL COMPANY AND DAVID A. VAN VLIET

ROBERT P. BERRY
BERRY & MAXSON, LLC
16150 MAIN CIRCLE DR.
SUITE 120
ST. LOUIS, MO 63017

F. JOSEPH WARIN
ANDREW TULUMELLO
JENNIFER J. SCHULP
JASON MORROW
GIBSON, DUNN & CRUTCHER LLP
1050 CONNECTICUT AVE., N.W.
WASHINGTON, DC 20036

Attorneys for Defendants-Appellees
KV Pharmaceutical Company and David A. Van Vliet

SUMMARY OF THE CASE AND REQUEST FOR ORAL ARGUMENT

This appeal concerns the dismissal of a putative class action asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a purported class of investors who purchased KV Pharmaceutical Company securities from June 15, 2004 to January 23, 2009. Plaintiffs allege that the Company and three individual Company executives made materially false and misleading statements and omissions regarding the Company's pharmaceutical manufacturing processes, which are subject to regulation by the Food and Drug Administration.

The District Court dismissed Plaintiffs' Complaint for failure to adequately plead any materially false or misleading statement or omission. The District Court also denied Plaintiffs' subsequent motion pursuant to Federal Rules of Civil Procedure 59(e) and 60(b)(2) to alter the judgment to permit Plaintiffs to file an amended complaint. Plaintiffs now appeal the District Court's dismissal and denial.

Because this appeal presents complex questions of securities law, Defendants respectfully request 20 minutes of oral argument per side.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Defendant KV Pharmaceutical Company states that it does not have a parent corporation, does not have any subsidiaries that are not wholly owned by the corporation, and that no public company owns ten percent or more of KV Pharmaceutical Company.

Defendant David A. Van Vliet is an individual, for whom disclosures are not required pursuant to Rule 26.1.

TABLE OF CONTENTS

Table of Contents
(Continued)

Page

Table of Contents
(Continued)

Page

Table of Contents
(Continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Table of Contents
(Continued)

Page

Table of Contents
(Continued)

Page

Table of Contents
(Continued)

Page

Statutes

Rules

Regulations

Other Authorities

Table of Contents
(Continued)

Page

STATEMENT OF ISSUES

1. Whether the District Court correctly dismissed the Complaint for failure to state a claim under Sections 10(b) and 20(b) of the Exchange Act, and Rule 10b-5(b) thereunder, because Plaintiffs failed to adequately plead the falsity of the alleged statements and omissions concerning KV's material compliance with FDA regulations and KV's financial results, or that these allegedly deceptive statements and omissions were made with scienter. *See* 15 U.S.C. §78u-4(b)(1)-(2); *In re 2007 Novastar Financial Inc. Sec. Litig*, 579 F.3d 878, 882 (8th Cir. 2009); *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1083 (8th Cir. 2005); *In re K-Tel Int'l Sec. Litig.*, 300 F.3d 881, 891 (8th Cir. 2002).

2. Whether the District Court correctly dismissed the complaint for failure to state a claim under Rules 10b-5(a) and (c) because Plaintiffs failed to adequately plead that Van Vliet engaged in a fraudulent scheme. *In re Charter Communications, Inc. Sec. Litig.*, 443 F.3d 987, 992 (8th Cir. 2006), *aff'd, Stoneridge Inv. Partners LLC v. Scientific Atlanta, Inc.*, 552 U.S. 148 (2008).

3. Whether the District Court correctly denied Plaintiffs' motion pursuant to Federal Rules of Civil Procedure 59(e) and 60(b)(2) seeking to amend their complaint. *Drobnak v. Andersen Corp.*, 561 F.3d 778, 788 (8th Cir. 2009); *U.S. ex rel. Roop v. Hypoguard*, 559 F.3d 818, 823 (8th Cir. 2009).

STATEMENT OF THE CASE

The District Court dismissed the Complaint, finding that Plaintiffs failed to allege with the required particularity that Defendants had made false or misleading statements regarding FDA compliance and financial results. *See* A-820, 823, 824, 826. The District Court also held that Plaintiffs failed to plead sufficient facts to establish that the Company or any individual defendant engaged in a scheme or course of conduct sufficient to establish a claim under Rule 10b-5(a) and (c). *See* A-828-30. The District Court also dismissed Plaintiffs' Section 20(a) claims against the individual defendants, holding that because Plaintiffs failed to plead with particularity a Section 10(b) or Rule 10b-5 claim against the individuals, a Section 20(a) claim could not be sustained. *See* A-830.

On March 18, 2010, Plaintiffs filed a motion to alter or amend the District Court's judgment pursuant to Federal Rules of Civil Procedure 59(e) and 60(b)(2), seeking leave to amend their Complaint and attaching a proposed amended complaint. A-833-1046. On October 20, the District Court denied Plaintiffs' motion because Plaintiffs did not conclusively establish that their second amended complaint would cure the deficiencies of their amended complaint. *See* A-1053.

Plaintiffs now appeal.

INTRODUCTION

Congress enacted the Private Securities Litigation Reform Act to tighten the standards in securities fraud cases "and *particularly* to put an end to the practice of pleading fraud by hindsight." *In re Navarre Corp. Sec. Lit.*, 299 F.3d 735, 742 (8th Cir. 2002) (emphasis added) (internal quotation omitted). The PSLRA imposed two new stringent pleading requirements on securities plaintiffs. First, plaintiffs must plead a strong inference of scienter. 15 U.S.C. § 78u-4(b)(2). Second, their complaint "shall specify each statement alleged to have been misleading" and "the reason or reasons *why* the statement is misleading." 15 U.S.C. § 78u-4(b)(1) (emphasis added). This second statutory command requires securities plaintiffs to "plead their allegations of fraudulent statements and omissions with particularity." *In re 2007 Novastar Financial Sec. Litig.*, 579 F.3d 878, 882 (8th Cir. 2009).

The Complaint fails to satisfy these standards. The Plaintiffs have attempted to manufacture a securities fraud case, dating back to 2004, from a 2009 FDA enforcement action. Plaintiffs recite a statement in the FDA's 2009 Complaint and Consent Decree that KV had a history of compliance problems and had received Forms 483 in previous years that were "the same as, or similar to" a 2009 Form 483. A-78, at ¶ 38. Based on nothing more than that allegation, Plaintiffs contend that regulatory compliance statements KV made in 2004, 2005, 2006, 2007, and

2008 were false. A-100-09, at ¶¶ 102-18. This is classic "fraud by hindsight" pleading—and it is not permitted under the PSLRA. The Plaintiffs do not allege any particularized facts showing *how* or *why* each specific statement challenged in the complaint was false when it was made, let alone that each statement was made with scienter. The District Court's dismissal should be affirmed for those reasons.

The District Court also properly denied the Plaintiffs' request for post-judgment leave to amend. The District Court had broad discretion to deny post-judgment leave to amend. It did so appropriately here, given that the amended complaint added cumulative allegations and failed to cure the deficiencies in the dismissed Complaint, as Plaintiffs represented it would.

STATEMENT OF FACTS

Lead plaintiffs ("Plaintiffs")—two pension plans for the public employees of Norfolk County, Massachusetts and the City of Boston—assert claims on behalf of a putative class of individuals who purchased KV securities from June 15, 2004 to January 23, 2009 (the "Class Period"), three days before KV announced that it had suspended all of its manufacturing activities. *See* A-68, 69 at ¶¶ 1-2, 6. Plaintiffs allege that KV and three Company executives violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 by making purportedly false and/or misleading statements or omissions concerning KV's compliance with FDA regulations and

concerning the financial performance of Generic Metoprolol, a drug that KV began to manufacture in mid-2007. *See*, *e.g.*, A-121-31, at ¶¶ 146-81.

A. The Regulatory Background And KV's Regulatory History

As a pharmaceutical manufacturer, KV operates in a highly regulated environment with strict oversight by the FDA. The FDA conducts periodic inspections of KV's operations to assess whether KV is producing "adulterated" drugs. One way in which a drug can be deemed "adulterated" is if it is not manufactured in accordance with current good manufacturing practices ("cGMP"). *See* 21 U.S.C. § 351(a)(2)(B). The FDA's cGMP regulations govern many aspects of the manufacturing process, including quality control procedures, equipment specifications, production controls, and record-keeping requirements. *See* 21 C.F.R. pt. 210.

At the end of an inspection, an FDA inspector may issue a Form 483 to the company. This form "lists observations made by the FDA representative(s) during the inspection of [the] facility. They are inspectional observations, and do not represent a final Agency determination regarding . . . compliance." *See* A-152 (2009 Form 483). If a company objects or plans to address any observations, it may submit information to that effect to the FDA. A-152 (same).

After the FDA reviews the results of the inspection, the agency completes an establishment inspection report ("EIR"). The FDA provides the report to the

company once the FDA has "closed" the investigation by making a final decision to take no administrative action. *See* 21 C.F.R. § 20.64(d)(3)(i) ("The consideration of regulatory enforcement action . . . shall be deemed to be closed . . . when a final decision has been made not to take such action or such action has been taken and the matter has been concluded."). If an inspectional observation is a matter of concern, and a more serious response is warranted, the FDA may issue a warning letter to a company, which the FDA describes as "an informal advisory . . . communicating the Agency's position on a matter but does not commit FDA to taking enforcement action." FDA Website, *About the Center for Drug Evaluation and Research > Enforcement Actions*, at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090279.htm. The FDA issues warning letters "for significant regulatory violations that require prompt and adequate corrective actions." *Id.*

According to the Complaint, KV received a Form 483 detailing inspectional observations after some inspections during the Class Period. A-78-79, at ¶ 38. The Complaint does not plead any specific observation, deficiency, or violation from any Form 483 during the Class Period. Forms 483 are publicly available—and they are routinely requested through the Freedom of Information Act. *See* 21 C.F.R. § 20.101(a). The record contains a FOIA log showing that many market participants requested the Forms 483 issued to KV for the Class Period. KV-47-

55. In their post-trial motion to amend the judgment, Plaintiffs submitted an expert declaration in which the expert acknowledges having been supplied "various redacted Form 483s" issued to KV. A-1028, at ¶ 2. Yet although Plaintiffs apparently have them, or could have requested them from the FDA, their Complaint does not allege a single specific fact about the content of, or statements in, any Form 483 issued to KV during the Class Period. Nor does the Complaint identify any specific conversation or the content of any discussion between the FDA and KV during the Class Period. Nor does the Complaint allege that the FDA issued any warning letters to the Company during the Class Period.

Instead, as the Complaint acknowledges, KV manufactured and sold products in the ordinary course during the Class Period. *See, e.g.*, A-71, 84, at ¶¶ 10, 55. KV also received new drug approvals during the Class Period (A-84-85, at ¶ 55-59), which, under FDA regulations, can occur only if the FDA determines that the manufacturer is in compliance with cGMP. *See* 21 U.S.C. § 355(j)(4)(A); 21 C.F.R. § 314.127. KV received 15 new drug approvals during the Class Period, including an approval on May 14, 2008.[1] And Plaintiffs point to no shutdowns,

---

[1] *See* FDA Public Registry of New Drug Approvals, at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=077176&TABLE1=OB_Rx; FDA Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations, at http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryah.cfm.

product recalls, suspensions, or other enforcement activity in 2004, 2005, 2006, or 2007. *See* A-79. The significant recalls in the fall of 2008 began—and were promptly disclosed—months *after* the last statement challenged in the Complaint. *See* A-94, 108-09, at ¶¶ 82, 115-18. The Plaintiffs do not allege that KV failed to timely or fully disclose the recalls in 2008. *See* A-100-09, at ¶¶ 102-18.

B. KV's Disclosures

Throughout the Class Period, KV filed its annual Form 10-K report with the Securities and Exchange Commission ("SEC"). Each Form 10-K—filed in 2004, 2005, 2006, 2007, and 2008—contained virtually identical language stating:

> We believe that all of our facilities are in material compliance with applicable regulatory requirements.

A-101-03, 105-08, at ¶¶ 104, 105, 106, 111, 114. The Forms 10-K also stated:

> We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.

A-101-03, 105-08, at ¶¶ 105, 106, 111, 114; *see also* A-101, at ¶ 104 (containing similar language).

KV's Forms 10-K also disclosed the pervasive nature of the FDA's regulatory oversight and the substantial risks of operating in a highly regulated market:

> Despite [its] ongoing efforts, cGMP requirements and other regulatory requirements, and related enforcement priorities and policies may evolve over time and we may not be able to remain continuously in material compliance with all of these requirements.

A-267, 276, 288, 322, 335. KV further disclosed the potential consequences that it might face if it were to be found to be in non-compliance with regulatory requirements:

> Non-compliance with applicable cGMP requirements or other rules and regulations of these agencies can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of government agencies to grant pre-market approval or other product applications and criminal prosecution.

A-267, 276, 288, 322, 335.

In July 2007, KV introduced a drug called Metoprolol. A-86, at ¶ 60. The complaint alleges that for the quarters ending September 30, 2007, December 31, 2007, and the first two quarters of 2008, KV committed securities fraud by reporting accurately to the market on the financial results of its overall operations, including its sales of Metoprolol. A-103-109, at ¶¶ 107-10, 112-13, 115-18.

C. KV's Recalls

In May 2008, the Company received field reports of oversized tablets of morphine sulfate. A-83, at ¶ 54(a). On June 6, 2008, the Company initiated a voluntary recall of a single lot of morphine sulfate 60 mg extended-release tablets and promptly disclosed this to the market. A-91, at ¶ 77. On June 13, 2008, and July 8, 2008, KV expanded the recall to include additional lots of differing dosages of morphine sulfate extended-release tablets. A-91, at ¶ 77. Again, KV promptly disclosed these recalls to the market. A-365 (referencing recalls in SEC Form 8-K

filed June 16, 2008); *see also* A-91 at ¶ 77. On October 15, 2008, the Company extended recalls to include specific lots of dextroamphetamine sulfate 5 mg tablets, and on November 7, 2008, to include specific lots of five additional products of various strengths. KV-38. On November 10, 2008, the Company recalled lots of 18 different products. KV-38. All of these recalls were promptly and fully disclosed and Lead Plaintiffs do not allege otherwise. *See* KV-34 (November 17, 2008 press release).

While these recalls were occurring, the Audit Committee of the Company's Board of Directors initiated an independent investigation into allegations of management misconduct and FDA regulatory compliance. The existence of the investigation was disclosed on August 11, 2008. A-90, at ¶ 75. The Company disclosed additional information about the investigation on November 12, 2008:

> [T]he Audit Committee of K-V Pharmaceutical Company . . . , with the assistance of legal counsel, including FDA regulatory counsel, and other advisers, is conducting an internal investigation with respect to a range of specific allegations, from multiple sources, involving, among other items, FDA regulatory and other compliance matters and management misconduct. One previously announced FDA recall of a Company product is associated with the investigation as are two new recalls involving several products dated November 7 and November 10, 2008. The Audit Committee presently intends to complete its investigation, deliver its findings and issue its recommended remedial actions before the end of December 2008.

A-377.

As a result of the Audit Committee investigation, on December 5, 2008, the Board of Directors terminated the Company CEO's employment agreement for cause. A-96, at ¶ 87. The Board also removed Hermelin from his position as CEO and Chairman of the Board, appointed Van Vliet as interim CEO, and named Terry Hatfield as Chairman of the Board. A-97, at ¶ 90.

D. The FDA Enforcement Action

On December 15, 2008, FDA inspectors began an inspection of ten KV facilities that lasted more than seven weeks. A-76, at ¶ 32. At the conclusion of the inspection on February 2, 2009, the inspectors issued a Form 483 to the Company, which detailed 35 observations. A-79, ¶ 40. The observations varied in severity and addressed issues including the Company's ability to manufacture consistent dosages of Hydromorphone HC1 tablets, A-157, and its quality control procedures in the manufacture of several product lines, *see* A-158-72. The Form 483 also noted many observations unrelated to manufacturing, such as the failure to file "field alerts," A-170-71, the failure to make written records of investigations into unexplained discrepancies, and the failure of a batch to meet specifications, A-163.

Meanwhile, as of December 19, 2008, the Company voluntarily suspended the shipment of its FDA-approved drug products in tablet form and also recalled a single lot of Hydromorphone HCl 2mg. A-393. On January 26, 2009, the

Company announced that three days earlier it had voluntarily suspended manufacture and shipment of all of the products it manufactured and announced a nationwide recall of most of its products. A-402.

On March 2, 2009, the FDA and Department of Justice filed a Complaint alleging that KV had "a history of continuing cGMP violations," and asserting that "[t]he deficiencies observed by FDA at the most recent inspection in February 2009, are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years." A-146-47. The FDA Complaint also alleged:

> Defendant's noncompliance has continued despite repeated warnings from FDA regarding its CGMP violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008, and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe CGMP violations at subsequent inspections.

A-147.

The FDA Complaint was resolved the same day by entry of a Consent Decree between the Government and the named defendants. A-190-224. Under the terms of the Consent Decree, the Company's manufacturing and distribution would remain suspended until the Company demonstrated compliance with cGMP. A-194. The Company agreed to hire an independent, third-party expert to certify

cGMP compliance, and the FDA would then make its own compliance determination. A-194, 198.

On February 25, 2010, ETHEX (KV's generic drug division) reached a plea agreement with the United States Attorney's Office for the Eastern District of Missouri and the Office of Consumer Litigation of the Department of Justice ("Plea Agreement"), resolving two felony counts of failing to file Field Alerts with the FDA regarding its products Dextroamphetamine Sulfate 5mg and Propafenone HCl 225 mg on or about September 16, 2008. A-1018-25. A Field Alert is a report that must be filed with the FDA within three working days of a drug manufacturer's discovery of information concerning a significant chemical change in distributed drug products or a failure of a distributed drug batch to meet specifications. 21 C.F.R. § 314.81(b)(1). The failure to file a Field Alert is not a cGMP violation. *See* 21 C.F.R. pt. 210. The failure to file these Field Alerts was at the direction of an unnamed KV executive, "Corporate Executive A," who disregarded the advice of certain employees to contact the FDA. *See* A-1018, 1021.

E. The District Court's Orders

1. The Motions To Dismiss

On February 22, 2010, the District Court dismissed the Complaint for its failure to comply with the PSLRA's heightened pleading requirements. A-804-32.

The District Court held that Plaintiffs "failed to allege with sufficient particularity that the compliance statements in the Form 10-K that the FDA issued to KV in 2004, 2005, 2006, 2007, and 2008 were false and misleading." A-819. The District Court observed that "the Form 483s issued to KV only contained observations—not 'a list of cGMP violations' as alleged by lead plaintiffs." A-819. The District Court also observed that "[e]ven assuming the observations listed in the Form 483s indicate that KV was not in material compliance" when KV received them from the FDA, "lead plaintiffs plead no specific facts that show that KV was not in compliance when KV filed each of the Form 10-Ks." A-820; Plaintiffs' Br. 28 n.7. The District Court also rejected Plaintiffs' allegations that KV had a duty to disclose the Forms 483. The District Court concluded that "[b]ecause the Forms 483 . . . from 2003 through 2008 were readily accessible to the public by submitting a request to the FDA . . . KV and Hermelin were under no duty to disclose these documents." A-825.

With respect to the financial disclosures about Metoprolol, the District Court found that "through the statements in the 2007 and 2008 press releases, 2008 Form 12[b]-25, and 2008 8-K, KV only reported its financial performance," and "did not attribute its financial success to its outstanding manufacturing processes or quality control measures associated with the production of the generic metoprolol." A-822. Accordingly, "[b]ecause KV chose only to speak about the financial status of

the company," and "lead plaintiffs do not allege that the figures reported in the financial statements were false and misleading," "lead plaintiffs have failed to allege with sufficient particularity that the financial statements . . . were misrepresentations." A-822, 823.[2]

The District Court also dismissed the Rule 10b-5(a) and (c) claims, finding that Plaintiffs "have failed to plead sufficient facts to establish that KV and Hermelin engaged in a scheme or course of conduct beyond the alleged misrepresentations and omissions," A-828, and that they "fail[ed] to allege with sufficient particularity how the scheme operated and how Van Vliet and Bleser were actually involved," A-829-30.

Finally, the District Court dismissed Plaintiffs' Section 20(a) claim against the individual defendants because Plaintiffs' failure to plead with particularity Section 10(b) and Rule 10b-5 claims, "the Court finds that lead plaintiffs cannot assert a claim under § 20(a) against them." A-830.

2. Plaintiffs' Motion To Alter Or Amend The Judgment

On March 18, 2010, Plaintiffs filed a motion pursuant to Federal Rules of Civil Procedure Rules 59(e) and 60(b)(2) seeking to amend the dismissed

[2] The District Court dismissed the Section 10(b) claims against Van Vliet and Bleser because lead plaintiffs "failed to allege with sufficient particularity that Van Vliet made a misrepresentation or omission" and "admit in their response brief that they '[d]id not allege that [Bleser] made any false and misleading statements.'" A-826 (alterations in original).

Complaint. A-833-1046. Plaintiffs attached to their motion an amended complaint, which added allegations with respect to the ETHEX plea agreement and affidavits from two proposed experts purporting to "cure the deficiencies" set forth in the District Court's dismissal order. A-836-41.

The District Court denied Plaintiffs' motion on October 20, 2010, holding that Plaintiffs "have not conclusively established that the second amended complaint would cure the deficiencies of the first." A-1053. The District Court explained that "[t]he primary basis for plaintiff's motion is the plea agreement," but that "[t]he admission by ETHEX in the plea agreement that the FDA was not notified through 'field alerts' regarding the oversized tablets was an allegation that was pled in the first amended complaint." *Id.* "Therefore," the District Court continued, "the plea agreement, at most, merely added evidentiary support for allegations that the Court was already treating as true." *Id.*

The District Court also stated that it was "unclear that the unlawful activities described in the plea agreement relate to the same time frame that is relevant in this matter"—given that the ETHEX plea agreement concerned conduct in September 2008 (A-1022) and the last statement challenged in the complaint was June 2008. A-108-09, at ¶¶ 115-17; A-1053. Finally, the District Court stated that the ETHEX plea agreement did not mention the Individual Defendants and that it is "highly questionable whether the second amended complaint would survive similar

motions to dismiss." A-1053. The Court accordingly denied the Plaintiffs' motion. *Id.*

SUMMARY OF ARGUMENT

The District Court properly dismissed the Complaint for failure to comply with the PSLRA's heightened pleading requirements for falsity. The PSLRA requires the Plaintiffs to allege, with respect to *each* statement alleged to be false, "the reason or reasons *why* the statement is misleading." 15 U.S.C. §78u-4(b)(1) (emphasis added). The Complaint does not meet this test. While Plaintiffs allege that KV received Forms 483 during the Class Period, they nowhere allege any particularized facts that would show *why* KV's statements about its cGMP compliance were false or misleading when those statements were made. Nor do Plaintiffs allege with particularity *why* disclosure of the Forms 483 was necessary to render KV's cGMP compliance statements non-misleading.

The District Court's dismissal order also can be affirmed on the alternative ground that Plaintiffs did not adequately plead a strong inference of scienter, as the PSLRA requires. *See* 15 U.S.C. §78u-4(b)(2). The Complaint's scienter allegations are conclusory (A-110-12, at ¶¶ 125-31) and purport to ascribe scienter to Defendants, including Van Vliet and Bleser, for acts that occurred several years before they joined the Company.

The District Court did not abuse its discretion in denying leave to amend. A District Court has considerable discretion to deny post-judgment leave to amend, and the District Court did not abuse that discretion in determining that Plaintiffs had failed to show the new complaint would cure the deficiencies of the old.

ARGUMENT

I. The District Court Did Not Err In Dismissing The Complaint.

A. Legal Standards For Pleading Falsity Under The Exchange Act.

At the outset, Plaintiffs fundamentally err in contending that the "pleading standard for falsity" is a mere "plausibility" that the challenged statements are false. *See* Plaintiffs' Br. 23, 29. Plaintiffs rely on the Supreme Court's decisions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), but those decisions involved Federal Rule of Civil Procedure 8, not the PSLRA. The PSLRA is a specialized pleading regime that "goes beyond the ordinary pleading requirements described in Rules 8(a)(2) and 9(b) of the Federal Rules of Civil Procedure[.]" *In re 2007 Novastar Financial Se. Litig.*, 579 F.3d 878, 882 (8th Cir. 2009). The PLSRA adopts "two *heightened* pleading requirements for securities fraud cases." *Navarre*, 299 F.3d at 741 (emphasis added). One requirement involves scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). The other "requires that the complaint specify *each* false statement or misleading omission and explain *why* the omission was

misleading." *Navarre*, at 741-42 (emphasis added); *see* 15 U.S.C. §78u-4(b)(1) (the complaint must "specify each statement alleged to have been misleading" and "the reasons or reasons why the statement is misleading").

Plaintiffs therefore err in suggesting that the PSLRA requires no more than what Rule 8 requires in the ordinary case. This Court has repeatedly held that falsity under the PSLRA must be pleaded with a demanding particularity. Plaintiffs must plead the "who, what, when, where, and how of the misleading statements or omissions." *Novastar*, 579 F.3d at 882 (internal quotation omitted). "The complaint's *facts* must necessarily show that the defendants' statements were misleading." *Novastar*, 579 F.3d at 882; *see also Detroit General Retirement Sys. v. Medtronic*, 621 F.3d 800, 805 (8th Cir. 2010) ("In other words, the complaint's facts must necessarily show that the defendant's statements were misleading") (quoting *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1083 (8th Cir. 2005)); *In re Amdocs Ltd. Sec. Litig.*, 390 F.3d 542, 549 (8th Cir. 2004) (Wallman, J., conc.) ("The facts contained in the complaint must *necessarily* show that the defendants' statements were misleading") (emphasis in original); *Navarre*, 299 F.3d at 742 (same).

Under this standard, this Court has affirmed the dismissal of complaints that lack "specific factual allegations demonstrating the reasons why the statement was false or misleading, as the PSLRA requires." *Novastar*, 579 F.3d at 883; *see also*

K-Tel Int'l Sec. Litig., 300 F.3d 881, 891 (8th Cir. 2002) ("A plaintiff must set forth, as part of the circumstances constituting fraud, an explanation as to why the disputed statement was untrue or misleading *when made*.") (emphasis in original).

Plaintiffs' opening brief does not cite the PSLRA—a unique strategy in a securities appeal. *See* Plaintiffs' Br. at ix, 12-55. And in urging reversal, Plaintiffs return, again and again, to the "plausibility" standard of Rule 8, without grappling with this Court's demanding particularity standards. *See* Plaintiff's Br. at 28 (suggesting the Complaint's allegations "support a plausible inference that those statements were false"); *see also id.* at 29 ("[I]t is 'plausible' . . . that KV's subsequent repeated statements of 'compliance' were false."). But the Rule 8 notice pleading standard applies in the absence of the PSLRA. It is not the standard under the PSLRA.[3]

---

[3] This Court's decisions are in accord with the views of other circuits with respect to post-*Twombly* and *Iqbal* pleading under the PLSRA and under the related standards of Rule 9(b). *See, e.g.*, *South Cherry Street, LLC v. Hennessee Group LLC*, 573 F.3d 98, 110 (2d Cir. 2009) (noting that the plausibility standard applies "as a general matter" to "all civil actions" but that, under the PSLRA, "the plaintiff must do more"); *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (noting in a "securities fraud case" the court does not apply the "standard set forth in *Bell Atl. Corp. v. Twombly*," and "[i]nstead, Shareholders must satisfy the heightened pleading rules codified in the PSLRA"); *SEC v. Tambone*, 597 F.3d 436, 442 (1st Cir. 2010) (Rule 9(b) represents "an additional hurdle" beyond pleader's plausibility requirements); *Am. Dental Ass'n v. CIGNA*, 605 F.3d 1283, 1291-93 (11th Cir. 2010) (ruling that pleading "does not plausibly, under *Twombly*, or particularly,

B. The Complaint Does Not Contain PSLRA-Compliant Allegations That KV's cGMP Statements Were False.

The Complaint challenges the falsity of two compliance statements by KV: (1) "We believe that all of our facilities are in material compliance with applicable regulatory requirements"; and (2) "We believe that we are currently in material compliance with cGMP and are registered with the appropriate agencies." A-101-109. Plaintiffs allege that these statements were materially false and misleading because KV was aware of Forms 483 previously issued to the Company, and those Forms 483 identified violations that were "'the same as, or similar to, prior violations.'" A-78-79, at ¶ 38. The Complaint relies on no reasons *other than* receipt of the Forms 483 in the relevant years as a basis for suggesting that these compliance statements were false. *See* A-100-08, at ¶¶ 102-14.

The District Court concluded that the Complaint "failed to allege with sufficient particularity that compliance statements in the Forms 10-K [filed by KV] in 2004, 2005, 2006, 2007 and 2008 were false and misleading." A-189. Plaintiffs take issue with this holding, *see* Plaintiffs' Br. at 28-33, but fail to identify "specific factual allegations demonstrating the reasons why [each] statement was false or misleading, as the PSLRA requires." *Novastar*, 579 F.3d at 883. The

---

under Rule 9(b)," meet pleader's obligations); *Chrichton v. Golden Rule Ins. Co.*, 576 F.3d 392, 395 (7th Cir. 2009) (noting that "in addition" to plausibility, a pleader alleging fraud must satisfy Rule 9(b)).

Complaint does not allege a single specific fact about the content of, or statements in, any Form 483 issued to KV during the Class Period in 2004, 2005, 2006, 2007, or 2008. Nor is there any specific factual allegation about any aspect of KV's business in 2004, 2005, 2006, 2007, or 2008 that would explain why the compliance statements issued in those years were misleading. In short, there are no particularized factual allegations *at all* that inform KV—or this Court—*why* the compliance statements for any given year were false. That pleading deficiency is fatal because the PSLRA demands that the plaintiffs plead "the reason or reasons why [each] statement is misleading." 15 U.S.C. §78u-4(b)(1).

Plaintiffs defend the Complaint by relying on the (untested) allegation in the FDA's Complaint that the Forms 483 for 2004 to 2008 made observations that were "the same as, or similar to" the FDA's Form 483 issued in February 2009. Plaintiffs' Br. 26 According to Plaintiffs, this allegation, standing alone, "explains exactly why [KV's] statements were false and misleading." Plaintiffs' Br. at 26. But these allegations do not satisfy the PSLRA's particularity requirement. In particular, this allegation—repeated over and over in the Complaint (*See, e.g.*, A-70, 78, 79, 101-07, at ¶¶ 8, 38, 104, 105, 106, 111)—does not detail *which* of the Forms 483, or which observations in the Forms 483, are "the same as, or similar to" those in the 2009 Form 483; does not indicate *when* such "same" or "similar" violations were occurring, or whether they were occurring at the time KV issued its

Form 10-Ks; does not indicate *how* such prior observations are "similar" to the 2009 observations; and does not specify whether they are similar in scope or magnitude, whether they involved similar products, or whether they involved similar areas or processes at KV's facilities. *Compare Novastar*, 579 F.3d at 882 (plaintiffs must plead the "who, what, when, where, and how of the misleading statements or omissions") (internal quotation omitted); *Navarre*, 299 F.3d at 743 (a complaint must allege "why these statements would have been false or misleading at the several points in time in which it is alleged they were made"); *Elam v. Neidorff*, 544 F.3d 921, 927 (8th Cir. 2008) ("plaintiffs again fail to allege any specific fact that would render the June statements false").

Moreover, it can be demonstrated conclusively that the purported "similarity" of the 2009 Form 483 and the Forms 483 issued in earlier years is impossible. Many of the observations in the February 2009 Form 483 relate to KV's manufacturing processes and quality control procedures regarding Metoprolol, a product which KV did not even introduce *until July 2007*. A-151-188, A-171. Thus, observations in the Forms 483 for 2004, 2005, 2006, and April 2007 cannot be "the same as, or similar to," the observations regarding Metoprolol in the February 2009 Form 483. Plaintiffs' allegations concerning KV's compliance statements therefore do not even satisfy the *plausibility* standard of Rule 8, let alone the demanding particularity requirements of the PSLRA.

Moreover, nowhere does the FDA Complaint and Consent Decree allege that KV was out of material compliance with cGMP in 2004, 2005, 2006, 2007, and 2008. That omission is also fatal, because KV stated in its Form 10-K that it was in "material" compliance with cGMP. *See* A-101-03, 105-08, at ¶¶ 104, 105, 106, 111, 114. The FDA Complaint and Consent Decree therefore do not demonstrate that KV's compliance statements were false at a high level of generality, let alone the required level of particularity.[4]

This is not a case where the Plaintiffs lacked access to the information necessary to plead fraud with particularity. The Forms 483 for the relevant period were easily accessible through the Freedom of Information Act (21 C.F.R. § 20.101(a); KV-45-46), and many market participants requested them. KV-48-55. Indeed, by their own account, Plaintiffs apparently have the Forms 483 issued to

---

[4] Plaintiffs cannot rely on the FDA Complaint or Consent Decree as an admission by KV. The Complaint contains untested allegations. The Consent Decree states that the signatories entered into it "solely for the purpose of settling this case, and without admitting or denying the allegations in the Complaint," A-191, and it accordingly cannot be considered an admission of the truth or accuracy of the FDA's allegations. *See Kushner v. Beverly Enterp., Inc.*, 317 F.3d 820, 830 (8th Cir. 2003) ("The government's sentencing memorandum is a position paper offered here by the investors for the truth of the matters asserted therein, which the defendants dispute. Such disputed papers should not be the subject of judicial notice on a motion to dismiss."). The FDA Complaint's characterization of the Forms 483 as the "same" or "similar" to previous violations may have been sufficient for Rule 8 purposes in the FDA's enforcement proceeding against KV, but that statement cannot satisfy the particularity requirement in a securities case under the PSLRA.

KV during the Class Period. The Plaintiffs' FDA "expert"—whose affidavit is attached as an exhibit to the proposed Second Amended Complaint (A-1027-32)—notes that Plaintiffs' counsel provided him with "various redacted FDA Forms 483" issued to KV. A-1028. Where Plaintiffs either have access to, or in fact have, the Forms 483 that would purportedly demonstrate the fraudulence of KV's compliance statements, and yet do not plead any facts about these Forms 483, their failure to plead the particularity requirements cannot be excused. *See Teachers Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 172 (4th Cir. 2007) (the PLSRA "authorize[s] the court to assume that the plaintiff has indeed stated *all* of the facts upon which he bases his allegation of a misrepresentation or omission") (emphasis in original).

C. The Complaint Does Not Contain PSLRA-Compliant Allegations That Nondisclosure Of The Forms 483 Violated Section 10(b).

The Plaintiffs contend that the failure to disclose the Forms 483 during the Class Period were "actionable omissions." Plaintiffs' Br. at 39; A-122, at ¶¶ 148-49. That claim fails for two reasons. First, Plaintiffs have not pleaded any facts demonstrating that disclosure of the Forms 483 was necessary in order to make KV's cGMP compliance statements not misleading. Second, as the District Court concluded (A-825), KV had no duty to disclose the Forms 483 because those documents were readily available to the public.

1. The Complaint Does Not Plead With Particularity Why Nondisclosure Of The Forms 483 Make KV'S Regulatory Compliance Statements Misleading

The federal securities laws do not impose a free-standing duty to disclose all information, or even all material information, to investors.[5] Rule 10b-5 makes actionable only those omissions of material fact that are "necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b).

Just as they fail to plead the falsity of KV's affirmative statements with particularity, Plaintiffs fail to plead with particularity why nondisclosure of the Forms 483 rendered KV's cGMP compliance statements misleading. The Complaint does not adequately plead that the Forms 483 contradict the accuracy of KV's statements about cGMP compliance, because there is no allegation about what information the Forms 483 contain *at all*. There can be no "actionable omission" where a complaint fails to allege *how* or *why* the information bears on the accuracy of statements the company has made. *See In re K-Tel*, 300 F.3d at 898 ("Materiality alone is not sufficient to place a company under a duty of

---

[5] *See Basic, Inc. v. Levinson*, 485 U.S. 224, 239 (1988); *Chiarella v. United States*, 445 U.S. 222, 232-33 (1980). "Silence, absent a duty to disclose, is not misleading under Rule 10b-5." *Sailors v. N. States Power Co.*, 4 F.3d 610, 612 (8th Cir. 1993). A duty to speak arises only "if there have been inaccurate, incomplete, or misleading disclosures." *Sailors*, 4 F.3d at 612.

disclosure"). Plaintiffs' "actionable omissions" claims therefore suffer from the same pleading deficiencies as their misrepresentation claims.

As a fallback argument, Plaintiffs contend that companies have a *per se* duty to disclose Forms 483. *See* Plaintiffs' Br. at 39. This is not the law. Plaintiffs' position would impose a radical obligation on every publicly traded pharmaceutical company to disclose every Form 483 they receive, no matter the context, and no matter what observations the Form 483 reports.

FDA-regulated entities do not have a *per se* duty to disclose Forms 483. Mere receipt of a Form 483 does not put a drug manufacturer out of material compliance with cGMP requirements. As the District Court observed, Forms 483 are *not* findings of regulatory noncompliance. A-819-20. Instead—as stated on the Forms 483 themselves—they contain "inspectional observations, and do not represent a final Agency determination regarding [the company's] compliance." A-152, 819. The FDA added this cautionary language to Forms 483 to clarify that the recipients were *not* deemed to be out of compliance with FDA regulations and to resolve any "perceived ambiguity [that might] result in inaccurate conclusions about the compliance of an inspected firm." A-819 (alteration in original).[6]

---

[6] This point is well understood in the lower courts. *See United States v. Utah Medical Products, Inc.*, 404 F. Supp. 2d 1315, 1318 (D. Utah 2005) ("A Form FDA-483 is a list of concerns observed by an FDA inspector during the course

Plaintiffs contend that Forms 483 document "violations" and not merely "observations" and that the District Court's "semantic distinction [between inspectional observations and violations] is unsupportable." Plaintiffs' Br. at 31. But whether Forms 483 report "observations," "deficiencies," or "violations" is beside the point. A Form 483 does not provide a final agency determination about the regulated entity's compliance, let alone material compliance, with FDA regulations—and for *that* reason there can be no *per se* rule that all Forms 483 must be disclosed. Just as public companies do not need to disclose every lawsuit filed against them, pharmaceutical companies do not need to disclose every Form 483 they receive. *See* 17 C.F.R. § 229.10; *see also* Item 103, Regulation S-K (stating that "ordinary routine litigation incidental to the business" need not be disclosed).

---

of an inspection. The investigator's observations are subject to review and response by the Company and are further reviewed by other FDA personnel before the FDA makes a decision whether it believes the Company complies with applicable law and regulations."); *Fujisawa Pharmaceutical Co., Ltd. v. Kapoor*, 16 F. Supp. 2d 941, 943 (N.D. Ill. 1998) ("Form 483s list observations made by an FDA inspector during an inspection of a plant. When a company receives a Form 483, it usually submits a written response to the FDA disputing or explaining the inspector's observations, or promising to correct the problem if the company agrees that it exists. Ordinarily, if the FDA finds the company's response acceptable, the FDA will take no further action. If the FDA finds the company's response unacceptable, the FDA may take further action such as the issuance of a regulatory letter."); *Bronstein v. Austin*, No. 07-C-3984, 2008 WL 4735230, *1 (N.D. Ill. May 30, 2008) (same).

The Plaintiffs cite a few cases in which courts held that a company had a duty to disclose Forms 483. *See* Plaintiffs' Br. at 39-40. But in each of those cases, the plaintiffs had pleaded with particularity why nondisclosure of the Forms 483 was misleading.[7] By contrast, the Complaint here does not do so; it makes no specific allegations about the contents of the relevant Forms 483 at all. The District Court joined the weight of authority in holding that the non-disclosures of the Forms 483 is not an actionable omission.[8]

---

[7] *In re Cryolife Inc. Sec. Litig*., No. 1:02CV1868-BBM, 2003 WL 24015055, at *2, *8 (N.D. Ga. May 27, 2003) (reviewing 12 specific observations from a Form 483); Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws at 29-35 *Wilkof v. Caraco Pharm. Labs., Ltd.*, 2010 WL 4184465 (E.D. Mich Feb. 11, 2010) (No. 09-12830), 2010 WL 1625949 (complaint devoted 17 paragraphs describing the Form 483 observations in detail); *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042 (W.D. Wash. Dec. 5, 2008) (receipt of Form 483 would delay launch of important product); *Yanek v. STARR Surgical Co*., 388 F. Supp. 2d 1110 (C.D. Cal. 2005) (same).

[8] *See, e.g., Anderson v. Abbott Laboratories*, 140 F. Supp. 2d 894 (N.D. Ill. 2001), *aff'd on other grounds sub nom Gallagher v. Abbott Laboratories*, 269 F.3d 806 (7th Cir. 2001) (nondisclosure of Forms 483 non-actionable, even where the FDA repeatedly noted shortcomings in Abbott's quality control policies and procedures and required Abbott to operate under a compliance plan, later issued a warning letter, and then demanded a recall of 125 products and imposed largest ever fine); *Acito v. Imcera Group, Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995) ("[P]ublicly disseminat[ing] the results of every inspection of every plant" by the FDA would be "unduly burdensome and impractical"); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 WL 3227767 at *11 (E.D. Penn. Nov. 1, 2006) ("[i]n a highly regulated industry," warnings from the FDA regarding regulatory compliance "are a reality of doing business" and requiring a company to disclose the results of all inspections may serve only "to bury the

2. KV Had No Duty To Disclose Forms 483, Which Are Publicly Available

Plaintiffs' "actionable omissions" theory also should be rejected for the separate and independent reason that the Forms 483 are publicly available. As the District Court recognized, "[t]he securities laws require disclosure of information *that is not otherwise not in the public domain.*" A-825 (quoting *Sailors*, 4 F.3d 610, 613 (8th Cir.1993)). This Court has repeatedly "held that Rule 10b-5 does not protect non-disclosed facts equally known *or available* to both parties." *Sailors*, 4 F.3d at 613 (emphasis in original) (quoting *Myzel v. Fields*, 386 F.2d 718, 736 (8th Cir. 1967)); *see also City Nat'l Bank v. Vanderboom*, 422 F.2d 221, 231 (8th Cir. 1970) (a company has no duty to disclose if investors have "ready access to the information involved"). As the District Court correctly concluded, because Forms 483 are "readily accessible to the public by submitting a request to the FDA," KV was under "no duty to disclose these documents." A-825.

Plaintiffs contend that "[a]ffirming this holding would be tantamount to turning the federal securities laws on their head" because the "fundamental purpose" of the Exchange Act is to implement a philosophy of "full disclosure."

---

material information companies currently disclose in a flood of red herrings. Such a result would scarcely protect investors"); *In re Boston Scientific Corp. Securities Litig.*, 490 F. Supp. 2d 142, 161 (D. Mass. 2007), *rev'd on other grounds sub nom Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75 (1st Cir. 2008) (finding *warning letters* to be "informal and advisory," and their nondisclosure not actionable).

Plaintiffs' Br. at 44. But Plaintiffs misapprehend the law. The securities laws do *not* require disclosure of information that is "equally known *or available* to both parties." *Sailors*, 4 F.3d at 613.

Indeed, this case is controlled by *Sailors*, which held that a company did not have a duty to disclose in circumstances directly analogous to those here. In *Sailors*, the plaintiffs contended that the defendant had a duty to disclose adverse developments in an administrative proceeding. This Court affirmed the dismissal of the complaint on the ground that information about the proceedings was "publicly available." *Sailors*, 4 F.3d at 613 ("We need not be concerned that [the defendant] chose to monitor [the proceedings] closely while investors such as Sailors apparently did not; public filings are equally available to all.").

That reasoning applies with equal force here. KV's Forms 10-K disclosed in detail that its operations were extensively regulated by the FDA, the risk FDA enforcement action, and the risk KV might not be able to remain continuously in material compliance with cGMP regulations. A-267, 276, 288, 322, 335. Just as the investors in *Sailors* were on notice of the administrative proceeding, the Plaintiffs here were on notice of the nature and scope of the FDA's oversight of KV. Here, as in *Sailors*, "all of the information [Plaintiffs] charge[] should have been disclosed [i.e. the Forms 483] was public information that could have easily been obtained by any investor." *Sailors*, 4 F.3d at 613. And here, just as in

Sailors, the "public filings [were] equally available to all." *Id.*; *see also* KV-47-55 (FOIA log).

The Plaintiffs also contend that "no one knew the Form 483s existed until they were ultimately disclosed by KV." Plaintiffs' Br. at 44. But that statement is belied by the public availability of the Forms 483 (*see* 21 C.F.R. § 20.101(a)), it does not appear in the Complaint, and it is demonstrably incorrect. The record contains a FOIA log showing that many market participants requested the Forms 483 issued to KV for the Class Period. KV-47-55. Moreover, in their post-trial motion to amend the judgment, the Plaintiffs submitted a Declaration from a Financial Analyst that includes excerpts from a December 2008 transcript of KV's phone call with stock analysts showing analysts asking about KV's pre-2009 Form 483 inspections. A-1040-41 (Analyst: "Could you give some specifics on the 43 observations during the FDA's last inspection?"). The representations Plaintiffs make to the Court in their appellate brief—"no one knew the Form 483s existed until they were ultimately disclosed by KV" (Plaintiffs' Br. at 44)—are contradicted by the record below and by the very filing Plaintiffs submitted in the District Court to re-open the judgment.

D. The Complaint Lacks PSLRA-Compliant Allegations That KV's Financial Reporting Was False.

In addition to the FDA compliance statements, Plaintiffs also challenge four company earnings announcements. Each of these statements, which Plaintiffs

characterize as "substantially identical for purposes of the motion to dismiss," Br. at 46, relate to KV's disclosure of financial information. *See* Plaintiffs' Br. at 46 (citing the four statements at A-103-06, A-108; ¶¶ 107, 109, 112, 115). Plaintiffs point to earnings releases on November 20, 2007, February 15, 2008, May 30, 2008, and August 11, 2008. *See Id.* Plaintiffs characterize these statements as consisting of "KV's quarterly earnings announcement[s] in which the stellar results by the Company are largely, if not entirely, ascribed to Generic Metoprolol." Plaintiffs' Br. at 46.[9]

The District Court correctly dismissed these claims on the ground that they were not false or misleading and that by reporting historical financial results KV did not undertake a duty to speak about its cGMP compliance. *See* A-822 (citing *K-Tel*, 300 F.3d at 898). Contrary to Plaintiffs' assertions in their appellate brief, the challenged statements do not "tout" "stellar results" or "link its financial success to a specific line of business"—they report past financial performance. *See*

---

[9] The Complaint challenges two statements in the August 11, 2008 Form 10-K. *See* A-108 at ¶¶ 115, 117. Plaintiffs have abandoned any claim that the District Court improperly dismissed the claim in ¶ 117. *See* Plaintiffs' Br. at 46; *Jenkins v. Winter*, 540 F.3d 742, 751 (8th Cir. 2008) ("Claims not raised in an opening brief are deemed waived"); *see also Chay-Velasquez v. Ashcroft*, 367 F.3d 751, 756 (8th Cir. 2004) ("Since there was no meaningful argument on this claim in his opening brief, it is waived."). The District Court dismissed the claim in paragraph 117 at A-823-24.

A-103-106, A-108 at ¶¶ 107, 109, 112, 115. For example, the November 20, 2007 press release reports:

> Net revenues for the second quarter increased 61% to $175.4 million, compared to $108.8 million for the second quarter of fiscal year 2007, with the Company's ETHEX generic/non-branded subsidiary reporting net revenue growth of 102% to $118 million.

See A-103 at ¶ 107. This press release reports historical financial information and does not address other subjects. The other press releases are "substantively identical." Plaintiffs' Br. 46. The District Court correctly recognized that in these releases "KV only reported its financial performance" and "did not attribute its financial success to its outstanding manufacturing processes or quality control measures associated with the production of generic metoprolol." A-822. The District Court also correctly concluded that the "financial statements did not discuss KV compliance with . . . FDA regulations." *Id.* Because "KV chose only to speak about the financial status of the company, KV was 'not required to dump all known information' about its manufacturing and regulatory issues." *Id.* at A-822, 823 (citing *K-Tel*, 300 F.3d at 898).

Without citing the PSLRA, Section 10(b), or Rule 10b-5, Plaintiffs urge this Court to adopt a blanket rule that the reporting of historical financial results triggers a duty to disclose "all information about that business that would alter the total mix of information." Plaintiffs' Br. at 48. This would dramatically expand the disclosure mandate under the Exchange Act and inject pervasive uncertainty

into the capital markets about issuer reporting requirements. If by reporting historic financial information a company is deemed to have a duty to disclose "all information about that business that would alter the total mix of information" (Plaintiffs' Br. 48), the securities laws will be effectively rewritten. *Compare K-Tel*, 300 F.3d at 898 ("Materiality alone is not sufficient to place a company under a duty of disclosure."); *Basic*, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). Since every public company must report its financial results under the Exchange Act, *see* Item 103, Regulation S-K, every company that mentions a product line or division when reporting financial results will trigger a duty to disclose "all information." Plaintiffs' Br. at 46. This is not the law.

Plaintiffs assert that a "long line of cases" requires a company to disclose all information about a business that would alter the total mix of information about that business when the company links its financial success to that business. *See* Plaintiffs' Br. at 48. These cases are non-binding, out-of-circuit decisions and do not support their proposition.[10]

---

[10] Plaintiffs also flatly misrepresent the holding of *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049 (9th Cir. 2008). Plaintiffs' Br. at 49. The Plaintiffs contend that "[t]he Ninth Circuit held that the failure to disclose off-label sales was actionable because Gilead chose to tout the drug as a primary driver of its earnings." *Id.* The Ninth Circuit did not so hold. Plaintiffs cite from the

Indeed, as the District Court concluded, the cases that Plaintiffs cite stand only for the non-controversial proposition, consistent with this Circuit's law, that information closely related to the subjects on which the defendant undertakes to speak is properly disclosed. *See* A-823 ("[T]he cases cited by lead plaintiffs are non-persuasive and distinguishable from this action because those cases involve withholding information closely-related to the company's public statements."). To the contrary, the courts have been vigilant in rejecting efforts by securities plaintiffs to establish the expansive duty to disclose that Plaintiffs propose. *See, e.g.*, *In re Sofamor Danek Grp., Inc.*, 123 F.3d 394, 401 n.3 (6th Cir. 1997) ("It is clear that a violation of federal securities law cannot be premised upon a company's disclosure of accurate historical data.").

KV provided complete and accurate information with respect to the financial information on which it undertook to speak; KV did not undertake to speak in its press release about production issues, manufacturing quality, or regulatory compliance. These claims were properly dismissed.

---

portion of the opinion reciting the complaint's allegations. *See* Plaintiffs' Br. at 49 (citing 536 F.3d at 1052); *see Gilead*, 536 F.3d at 1050 ("Taking its allegations as true, the complaint tells the following story about Gilead and its marketing practices."). *Gilead* dealt with loss causation, not the duty to disclose. *See* 536 F.3d at 1056-58. Yet Plaintiffs criticize the District Court for "not address[ing], or let alone distinguish[ing], the case." Plaintiffs' Br. 50.

E. Plaintiffs Failed To State A Claim Under Rules 10b-5(a) and 10b-5(c).

Plaintiffs next assert that the District Court improperly dismissed their "scheme liability" claims under Rules 10b-5(a) and (c) with respect to Defendant Van Vliet, because "the Complaint alleges that **all** Defendants sued by the FDA, including Van Vliet and Bleser, were responsible for KV's violations and noncompliance." Plaintiffs' Br. at 53 (emphasis in original). As the District Court held, however, Plaintiffs "fail to allege with sufficient particularity how the scheme operated and how Van Vliet [was] actually involved," A-829-30, and the claim was properly dismissed.[11]

In order to state a claim under Rules 10b-5(a) or (c), a plaintiff must allege a "scheme . . . to defraud" or a "course of business which operates . . . as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5. Federal Rule of Civil Procedure 9(b) requires Plaintiffs to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also In re Parmalat Sec. Litig.*, 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006) (Rule 9(b) requires a plaintiff to "specify, with particularity, what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had

---

[11] Plaintiffs have abandoned any challenge to the District Court's dismissal of the Rule 10b-5(a) and (c) claims against Defendants KV and Hermelin. *See* Plaintiffs' Br. at 52-55; *see also Jenkins*, 540 F.3d at 751 (waiver in opening brief); *Chay-Velasquez*, 367 F.3d at 756 (same).

on the securities at issue.") (internal quotation omitted). Plaintiffs fail to meet these standards.

Plaintiffs' two interconnected arguments in support of their position are unavailing. First, they assert that Van Vliet was the head of ETHEX during the time period in which the alleged fraud occurred, and thus must have been a party to a scheme. Second, Plaintiffs argue that they plead in their Complaint "specific factual allegations, which explain that Defendant**s**, plural, all participated in the scheme violating FDA regulations." Plaintiffs' Br. at 55 (citing A76-84). The allegations in the Complaint against Van Vliet, however, stem from his status as a defendant in the FDA Complaint. Neither the Complaint nor the FDA Complaint separately delineates any fraudulent act or scheme employed by Van Vliet specifically. Merely referring to a group of defendants, without alleging facts regarding their individual contributions to the scheme, is insufficient to plead fraud with particularity. *See, e.g., City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 690 (6th Cir. 2005) (holding that a complaint that alleged only that the defendant was a high-ranking corporate officer, but did not allege that he "played any role" in the alleged fraud was insufficient).

Plaintiffs' position is also nonsensical when Van Vliet's personal circumstances are examined: The Complaint alleges that "Defendants knew, since at least *early-2003*, that KV was in violation of numerous FDA regulations." A-

78, at ¶ 38 (emphasis added). These allegations cannot possibly apply to Van Vliet, who had no relationship with the Company until he was hired in 2006. Such vague pleading is insufficient to survive a motion to dismiss with respect to the Rule 10b-5(a) and (c) claims against Van Vliet, and the District Court correctly dismissed the claim against him.

II. Dismissal Of The Complaint Was Also Proper Because It Does Not Adequately Plead Scienter Under The PSLRA.

The District Court's judgment should be affirmed for the reasons set forth above. In the alternative, the judgment also can be affirmed on scienter grounds. *See, e.g.*, *McAdams v. McCord*, 584 F.3d 1111, 1113-14 (8th Cir. 2009) ("This court . . . may affirm the district court's judgment on any basis supported by the record.") (quotation omitted).

Under the PSLRA, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). *Tellabs* requires courts to "consider, not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged[.]" *Id*. at 314. The PSLRA requires courts to determine that any inference of scienter be "cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Id*. To make that determination, courts must engage in an "inherently comparative" analysis—that is, they must "consider plausible non-

culpable explanations for the defendant's conduct" and balance the strength of those explanations against the strength of the inference that the defendant acted with scienter. *Id*. at 323-24; *see also Elam v. Neidorff*, 544 F.3d 921, 928 (8th Cir. 2008).

The Complaint's scienter allegations are exceedingly threadbare and conclusory. *See* A-110-12, at ¶¶ 125-31. There are no specific scienter allegations regarding Van Vliet *at all*—the dismissal of the claims against him should be affirmed for that reason alone. As to KV, the Complaint bases scienter on the same allegations it uses for falsity—namely, the FDA Complaint and Consent Decree, and in particular the statement in the FDA Complaint that "[t]he FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies." *See* A-111, at ¶ 127 (emphasis removed).

The inference of scienter arising from the FDA Complaint is weak at best. Even if these untested allegations are accepted as true, the FDA Complaint does not specify which defendants had knowledge of the Forms 483 at the times that they were issued. Van Vliet was not a KV employee until 2006 (A-73, at ¶ 20), and Bleser did not begin her employment until 2007 (A-74, at ¶ 22).

Moreover, Plaintiffs plead no particularized facts giving rise to a "strong inference" that any defendant acted with scienter at the time the challenged

statements were made during the Class Period. The Complaint alleges that the defendants had received Forms 483 (A-79, at ¶ 38), but it does not allege the contents of these Forms 483, or allege that the Forms 483 placed KV out of material compliance with cGMP regulations. To establish scienter, the complaint's factual allegations must demonstrate that the defendants knew that their public statements were false *when they were made*. *See K-Tel*, 300 F.3d at 891 (the complaint must allege "why the dispute statement was untrue or misleading *when made*") (emphasis in original). The PSLRA's pleading standards cannot be satisfied by pleading "fraud by hindsight," which is precisely what the Complaint alleges here. *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 742 (8th Cir. 2002); *In re Discovery Labs. Sec. Litig.*, 2007 WL 789432, at *6 ("Plaintiffs cannot use a statement made in April 2006 to prove the falsehood of a statement made in March 2005.").

Moreover, under *Tellabs*, the weak inferences flowing from the Complaint must be compared to the "plausible non-culpable explanations for the defendant's conduct" that also arise from the Complaint. *Tellabs*, 551 U.S. at 324. Here, the inferences of non-culpable conduct are powerful and cogent.

First, the FDA repeatedly approved new drug applications during the Class Period, including as late as May 2008. *See supra*, note 1. As Plaintiffs note, the FDA approved Generic Metoprolol in May 2007, only a month after the April

2007 Form 483. A-85, at ¶ 58. The FDA cannot approve those applications unless it determines the Company is in compliance with cGMP. *See* 21 U.S.C. § 355(j)(4)(A); 21 C.F.R. § 314.127. The most likely inference is that the FDA viewed KV's manufacturing facilities as cGMP compliant at the time it approved Metoprolol, as well as at the time it approved more than a dozen other drugs during the class period. *See supra*, note 1.

Second, Plaintiffs have not alleged—because they cannot—that the FDA did not "close" each of its inspections of KV and issue the corresponding EIRs, which indicate that the FDA intends to take no further enforcement action. This is because the FDA, in fact, *did* close each inspection with an EIR—Def. Hermelin's Mem. of Law in Supp. of Mot. to Dismiss Pls.' Consolidated Am. Compl. at 14—which Plaintiffs simply elected to ignore. The Plaintiffs' failure to plead any facts suggesting that FDA viewed its inspections as "open" or "unresolved" gives rise to the inference that it viewed KV as materially compliant with cGMP regulations at the end of its inspections, even if KV was working to resolve selected inspectional observations.

Third, Plaintiffs have not alleged—and they cannot—that the FDA issued any warning letters to KV as a result of its inspections. Again, the most plausible inference is that the FDA did not determine that any of the observations that it made of KV's cGMP compliance required enforcement action, which supports

KV's statements during the Class Period that it believed that it was in material compliance with cGMP regulations.

Fourth, the Complaint nowhere alleges that the FDA ever, at any time during the Class Period, informed KV that it was *not* in material compliance with cGMP regulations. Again, the most plausible inference is that KV and FDA believed that KV *was* in material compliance.

Finally, the Forms 483 were publicly available and, as the record demonstrates, accessed by market participants. KV-48-55. The public availability and dissemination of the Forms 483 strongly undercuts any inference that the defendants acted with an intent to defraud by not disclosing them.

Taken together, the inferences that arise from the FDA's drug approvals, the absence of warning letters and of allegations that the FDA told KV during the Class Period it was not in compliance with cGMP regulations, and the absence of allegations that the FDA inspections were held open, plainly overpower and are more "cogent" than any inference of scienter. *Tellabs*, 551 U.S. at 314. The dismissal of the Complaint can be affirmed on this ground.

III. The District Court Properly Denied Plaintiffs' Motion To Alter Or Amend The Judgment

The District Court properly denied Plaintiffs' motion pursuant to Federal Rules of Civil Procedure 59(e) and 60(b) to file an amended complaint. That

decision was committed to the District Court's discretion, and the District Court did not abuse its discretion in denying the motion.

A. Legal Standard Governing Post-Judgment Motions For Leave To Amend

Plaintiffs contend that the District Court's denial of the motion for leave to amend should be reviewed *de novo*. Plaintiffs' Br. at 55. That is incorrect. The disposition of a post-judgment motion for leave to amend is committed to the district court's discretion, and this Court applies abuse of discretion review to these decisions. *See Drobnak v. Andersen Corp.*, 561 F.3d 778, 787 (8th Cir. 2009). Abuse of discretion review means that "the [district] court has a range of choice, and its decision will not be disturbed as long as it stays within that range[,] is not influenced by any mistake of law or fact, or makes a clear error of judgment in balancing relevant factors." *Palmida, Inc. v. E.S. Originals, Inc.*, 281 F.3d 726, 729 (8th Cir. 2002). This Court is "not to substitute [its] judgment for that of the district court" (*Brunsting v. Lutsen Mountains Corp.*, 601 F.3d 813, 823 (8th Cir. 2010)) and "will affirm unless no reasonable person could agree with the district court." *Higgins v. Apfel*, 222 F.3d 504, 505 (8th Cir. 2000).

In *Roop*, this Court analyzed the standards governing post-judgment motions for leave to file an amended complaint. *See Roop*, 559 F.3d at 823-25. The Court recognized that, in the post-judgment context, some circuits applied the Rule 15(a) "freely give" standard without alteration. *Id.* at 823. The court stated that this

circuit's precedent is different, and more stringent, because "interests of finality dictate that leave to amend should be less freely available after a final order has been entered." *Id.* at 823. The Court stated that "from this survey of prior case law, we conclude that district courts in this circuit have *considerable discretion* to deny a post-judgment motion for leave to amend because such motions are disfavored, but may not ignore the Rule 15(a)(2) considerations that favor affording the parties an opportunity to test their claims on the merits[.]" *Roop*, 559 F.3d at 824 (emphasis added). This Court has affirmed the denial of post-judgment motions for leave to amend for a variety of reasons under this standard..[12]

The District Court relied extensively on *Roop* (A-1052), yet Plaintiffs do not trouble to cite or address that case in their brief. *See* Plaintiffs' Br. 55-62. The District Court followed *Roop*, stating it was "mindful of the Rule 15(a)(2) considerations favoring disposition of claims on the merits," before explaining why

---

[12] *See Drobnak*, 561 F.3d at 788 ("Given the shifting theories of liability, the absence of factual support, and plaintiffs' less-than-forthcoming approach to this case, we conclude the district court's frustration was well founded and that its dismissal with prejudice was appropriate"); *Charter Communications*, 443 F.3d at 993 ("Here, plaintiffs argued that the district court overlooked or misapplied prior decisions from district courts in other circuits. The district court briefly reviewed those cases and concluded it 'is not inclined to reach a different result.' Denial of the motion to reconsider on this ground was not an abuse of discretion"); *K-Tel*, 300 F.3d at 899-900 ("we find the abuse of discretion standard is applicable because rather than find a specific allegation futile as a matter of law, the district court found it futile to amend where no actual amendments were possible").

in the exercise of its discretion it would deny Plaintiffs' motion. A-1052. It did not err in doing so.

B. The District Court Did Not Abuse Its Discretion With Respect To Arguments That Plaintiffs Waived.

Plaintiffs' initial motion seeking relief from the District Court's judgment did not set forth any of the grounds Plaintiffs now contend are important to the leave-to-amend analysis. The motion did not mention any additional allegedly false statements and was largely devoid of any legal analysis at all. That motion's "Legal Argument" merely recited the standard for Rule 59(e) and 60(b)(2) motions, and then asserted that the ETHEX plea agreement was new evidence. A-838-39.

Plaintiffs now fault the District Court for not addressing in its Order a new allegedly false statement and new facts that they included in their Proposed Second Amended Complaint. Plaintiffs' Br. at 57. Because Plaintiffs did not raise these arguments in their initial motion, the District Court was within its rights not to consider them. *Roth v. G.D. Searle & Co.*, 27 F.3d 1303, 1307 (8th Cir. 1994) (quoting *Stafford v. Ford Motor Co.*, 790 F.2d 702, 706 (8th Cir. 1986) ("The district courts cannot be expected to consider matters that the parties have not expressly called to their attention, even when such matters arguably are within the scope of the issues that the parties have raised.")

In *Roop*, this Court held that the district court was not required to undertake a detailed analysis of whether an amended complaint was futile where the plaintiff's "supporting memorandum did not explain how [the] lengthy [amended] pleading—on its face substantially similar to the initial Complaint—cured the Rule 9(b) deficiencies in the initial Complaint." *Roop*, 559 F.3d at 824. "The [district] court was not obligated to ferret out well-hidden changes in a post-judgment amended pleading without guidance from [the plaintiff]." *Id.* Although the Plaintiffs submitted a lengthier reply brief, in these circumstances, there was no abuse of discretion in denying the post-judgment motion. *See Travelers Prop. Cas. Co. of Am. v. Hillerich & Bradsby Co., Inc.*, 598 F.3d 257, 275 (6th Cir. 2010) ("Arguments raised only in reply, and not in the original pleadings, are not properly raised before the district court, and so are also not properly preserved for appeal.").

C. Plaintiffs' Proposed Amended Complaint Did Not Cure The Deficiencies In The Complaint The Court Dismissed.

Motions under Rules 59(e) and 60(b)(2) are available only when "exceptional circumstances warrant[] post-judgment relief." *Arnold v. Wood*, 238 F.3d 992, 998 (8th Cir. 2001). They serve only "a limited function: to correct manifest errors of law or fact or to present newly discovered evidence." *Arnold v. ADT Security Servs., Inc.*, 627 F.3d 716, 721 (8th Cir. 2010). These motions upset the finality of the judgment, and are viewed with disfavor. *See Roop*, 559 F.3d at

823; *Baxter Intern., Inc. v. Morris*, 11 F.3d 90, 92 (8th Cir. 1993). To prevail on such a motion, the movant must show: "(1) that the evidence was discovered after trial; (2) that the party exercised due diligence to discover the evidence before the end of trial; (3) that the evidence is material and not merely cumulative or impeaching; and (4) that a new trial considering the evidence would probably produce a different result." *Atkinson v. Prudential Prop. Co.*, 43 F.3d 367, 371 (8th Cir. 1994).

Plaintiffs' "new" evidence fails because it was not new, was cumulative, and would not have affected the District Court's judgment. The district court correctly concluded that Plaintiffs had not provided "a sufficient basis for vacating the dismissal order." A-1053.

1. The Proposed Amendments Concerning the ETHEX Plea Agreement Contained Old, Cumulative Evidence.

Plaintiffs primary addition in their proposed amended complaint relates to the purported "revelation" after the case was dismissed that KV's subsidiary, ETHEX, "pled guilty to two criminal felony counts that arise out of the same conduct that forms the basis of certain claims here." A-836; Plaintiffs' Br. at 56. In sum, the Plea Agreement states that ETHEX "failed to notify the FDA through 'field alerts' of the discovery of oversized tablets of Propafenone and Dextroamphetamine" in September 2008. A-1052-53; *see also* A-882-83, 885-86

at ¶¶ 113-15, 117, and 125-26. According to Plaintiffs, the proposed amended complaint "alleged for the first time that KV engaged in a criminal cover-up of its manufacturing problems *starting in May 2008*," based on the Plea Agreement. Plaintiffs' Br. at 56 (emphasis added).

But these purportedly "new" facts relating to a "cover-up" starting in May 2008 add nothing material to the story Plaintiffs had already told in the Complaint dismissed by the District Court. Indeed, Plaintiffs specifically alleged the failure to file Field Alerts in their Complaint:

> *KV concealed from FDA* the production of oversized Morphine Sulfate tablets discovered *on or about May 15, 2008*. No field alert was ever filed and KV did not notify FDA until October 10, 2008. FDA requires the submission of a "FDA Field Alert" within three days of such a finding. *KV did not notify the FDA despite the fact that it knew that at least 10 more products had oversized tablets, including* Isosorbide, *Propafenone, Dextroamphetamine Sulfate Tabs*, and Piaratase.

A-83, at ¶ 54(a) (emphasis added). Plaintiffs also attached to the Complaint a copy of the February 2, 2009 Form 483, which makes the exact same allegation:

> As part of your investigation of oversized Morphine Sulfate tablets, which was initiated *on/about 15 May 2008*, you sorted all tablet products on hand and found oversized tablets with at least 10 more products. *No field alert was ever filed and FDA was not notified until 10Oct2008*. Products include:
>
> - Isosorbide 30 mg and 60 mg
> - *Propafenone* HCl Tabs 150 mg and 225 mg
> - *Dextroamphetamine Sulfate Tabs 5 mg*
> - Plaratase 8000 Tabs

A-171 (emphasis added). Thus, there is nothing new about these "cover up" allegations, which had already been considered by the District Court.

The proposed amended complaint, according to Plaintiffs, also sought to tie these "new facts" to a "new misrepresentation." Plaintiffs point to a "new" false statement made by KV on August 11, 2008: "[m]anagement is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company's financial results." Plaintiffs' Br. at 57 (citing A-895, at SAC ¶ 148). But this, too, is simply not new—the Complaint made the *exact same allegation*:

> The first inkling of the Company's impending shutdown came *on August 11, 2008*, when KV disclosed that the Audit Committee of its Board of Directors had commenced an independent investigation into allegations of management misconduct. *Management reported the inquiry as part of its quarterly earnings report, and sought to downplay its significance by saying it did not believe that there had been any misconduct that would have a material financial impact.*

A-68-69, at FAC ¶ 3 (emphasis added). The Complaint went on to dedicate *seven* paragraphs to KV's August 11 statements (A-68-69, 90-91, 108-09, at ¶¶ 3, 75, 77, 115-18), and explicitly alleged that the statements were "materially false and misleading." A-109, at ¶ 118.[13]

---

[13] Plaintiffs further argued below that the Plea Agreement conclusively established that the failure to file field alerts "(i) constituted criminal violations, (ii) with 'intent to defraud and mislead.'" A-839. But, again, the Complaint was rife with identical allegations of the same criminal activity and

The district court did not abuse its discretion in finding that "[t]he admission by ETHEX in the plea agreement that the FDA was not notified through 'field alerts' regarding the oversized tablets was an allegation that was pled in the first amended complaint." A-1053. At most, the Plea Agreement lends support to allegations already treated by the district court as true when it dismissed the Complaint. *See* A-1053; *see also Hicks v. Six Flags Over Mid-America*, 821 F.2d 1311, 1317 (8th Cir. 1987) (rejecting a Rule 60(b) motion because the "additional testimony" proffered by the plaintiff "would merely have been cumulative"). The district court was within its discretion to reject amendment based on old, cumulative, and previously considered facts and allegations.

2. The Proposed "Expert Affidavit" is Improper and Would Not Have Produced a Different Result.

Plaintiffs also contend that the "expert affidavit" of Benjamin L. England attached to their proposed amended complaint would "cure the deficiencies set

---

management misconduct. *See, e.g.*, A-76-77, ¶ 33 (alleging that the February 2009 Form 483 detailed "a plethora of illegal activity"); A-96-97, ¶¶88-90 (alleging that KV's former CEO was terminated "for cause" because he breached his fiduciary duties to the Company).

In addition, the Criminal Information to which ETHEX pled guilty only addressed conduct after May 7, 2008. *See* A-1019. Nothing in the Plea Agreement or the Information addresses earlier events. A-1053. The district court accordingly reasoned that "it is unclear that the unlawful activities described in the plea agreement relate to the same time frame that is relevant in this matter." A-1053.

forth in the Court's Memorandum and Order." A-839; Plaintiffs' Br. at 57-58. The district court, however, did not err by failing to permit amendment in light of Plaintiffs' "expert affidavit." This affidavit does not resolve the deficiencies identified in the Memorandum and Order.

As an initial matter, the England Affidavit does not contain any information that was unavailable to Plaintiffs before judgment was entered. Plaintiffs make no attempt to justify their failure to present this affidavit before dismissal. Motions for reconsideration "are not to be used to introduce new evidence that could have been adduced during pendency of the motion at issue." *Arnold v. ADT Sec. Serv., Inc.*, 627 F.3d, 716, 721 (8th Cir. 2010) (internal quotations omitted).

Moreover, the England Affidavit's citations to and interpretations of federal statutes, Forms 483, and the FDA's Investigations Operations Manual were repetitive of arguments Plaintiffs had already made to the District Court in their opposition to Defendants' motions to dismiss. A-450. A district court does not abuse its discretion in denying a motion for leave to amend to make arguments that already have been made.

Finally, nothing in the England Affidavit cures the deficiencies of the Complaint. A-1027-32. The England Affidavit addresses whether Form 483s indicate "violations" or "deficiencies." Plaintiffs assert that the district court's

dismissal was based on a finding that the Forms 483 only contained "observations," not a list of cGMP "violations." Plaintiffs' Br. at 57-58. They argue that the England Affidavit cures that deficiency by opining that "the use of the terms 'violations,' 'deficiencies' and 'observations' is interchangeable" (A-839-40), and that "FDA inspectors . . . are collecting evidence of violations as a matter of law and a matter of course." A-1031, at ¶ 10.

But whether the FDA inspectors collected "evidence" of violations does not affect the District Court's analysis. The District Court specifically found that the disclaimer on the face of every Form 483 states that it "lists *observations* made by the FDA representative during the inspection," and that such observations "*do not represent a final determination regarding [a company's] compliance*." A-819. As such, while Forms 483 may constitute, in the opinion of the individual inspector, *evidence* of violations, they do not establish non-compliance—much less material non-compliance—with cGMP.

The District Court, moreover, went one step further, and found that even assuming the Forms 483 had shown that the Company was not in material compliance at the time of the FDA inspection, Plaintiffs "plead no specific facts that show that KV was not in compliance when KV filed each of the Form 10-Ks." A-820. The England Affidavit did not address this point (A-1027-32), and

even if the District Court were to have credited England's remarks, the outcome would not have been altered.[14]

3. The Proposed Amendment Does Not Cure Defects in Claims Against David Van Vliet.

Plaintiffs concede that the proposed amended complaint offers no new allegations against Defendant Van Vliet. Plaintiffs' Br. at 59. The District Court dismissed all three counts in the Complaint against Van Vliet for failure to allege facts that would show him to have been responsible for any misrepresentations or omissions or to have participated in any scheme to defraud. A-826, 830. With no new facts or allegations, Plaintiffs have no basis to reopen the case against Van Vliet.

D. Rule 15(a) Considerations Have Diminished Force Under the PSLRA

Several courts have held the Rule 15(a)(2) considerations have less force when a complaint is dismissed pursuant to the PSLRA. This is due to the PSLRA's demanding pleading standards, 15 U.S.C. § 78u-4(b)(1)-(2); its discovery stay, 15 U.S.C. § 78u-4(b)(3)(B); its statutory command to dismiss a complaint that does not meet the statutory pleading requirements, 15 U.S.C. § 78u-4(b)(3)(A); and its lead plaintiff provisions, which are designed to facilitate the

---

[14] Plaintiffs have not addressed the Preston Affidavit they submitted with their proposed amended complaint and have waived any argument that it would cure any defects in the Complaint.

appointment of sophisticated lead plaintiffs who will thoroughly investigate the claims, 15 U.S.C. § 78u-4(a)(3)(B).

These statutory provisions evidence Congress' intent, in enacting the PSLRA, to ensure that many securities cases be resolved on the sufficiency of a complaint drafted by sophisticated lead plaintiffs and without the aid of discovery. As the Sixth Circuit has stated, the "pleading requirement is more than simply a line the plaintiffs must cross to get to discovery; it is the heart of the PSLRA." *Miller v. Champion Enters.*, 346 F.3d 660, 691 (6th Cir. 2003). The PSLRA's "stringent requirement operates to discourage baseless suits altogether" and "evinces Congress' acknowledgement of the burden an allegation of securities fraud place on the innocent defendant even without discovery." *Id.* To that end, the PLSRA's uniform pleading standard "becomes meaningless if judges on a case-by-case basis grant leave to amend numerous times." *Id.* at 691.

Accordingly, some circuits have held that "allowing repeated filing of amended complaints would frustrate the purpose of the PSLRA," and that any "tension between Rule 15(a) . . . and the PSLRA" must be resolved in "favor of the PSLRA" because given Congress' intent and the PSLRA's requirements, "it is correct to interpret the PSLRA as restricting the ability of plaintiffs to amend their complaint, and thus as limiting the scope of Rule 15(a)." *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 700 (6th Cir. 2004); *Cal. Pub. Emps.' Ret. Sys. v. Chubb*

Corp., 394 F.3d 126, 164 (3d Cir. 2004) (PSLRA has the "unique impact of narrowing application of [the 'freely given'] standard in securities fraud cases").

Roop involved a claim under Rule 9(b), not a claim under the PSLRA. It advised district courts to be cognizant of Rule 15(a) considerations in evaluating post-judgment motions for leave to amend, which the District Court here plainly was. Indeed, if anything, the District Court's mindfulness of Rule 15(a) considerations here went beyond what is required after a dismissal under the PSLRA. *See P.R. Diamonds*, 364 F.3d at 700; *Chubb Corp.*, 394 F.3d at 164. The Plaintiffs here already had amended once—as was their right. The District Court's decision to deny them a third bite at the apple should be affirmed.

CONCLUSION

For the foregoing reasons, the judgments of the District Court should be affirmed.

Respectfully Submitted,

Dated: March 15, 2011

/s/ Andrew S. Tulumello
F. Joseph Warin
Andrew S. Tulumello
Jennifer J. Schulp
Jason E. Morrow

/s/ Robert P. Berry
Robert P. Berry

BERRY & MAXSON, LLC
16150 Main Circle Drive, Suite 120
St. Louis, Missouri 63017

GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue N.W.
Washington, District of Columbia
20036
Telephone: (202) 955-8500
Facsimile: (202) 467-0539

Telephone: (314) 480-5882
Facsimile: (314) 480-5884
rberry@berrymaxson.com

Attorneys for Defendants-Appellees KV Pharmaceutical Company
and David A. Van Vliet

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C)(i), I hereby certify that the foregoing Brief for Defendants-Appellees KV Pharmaceutical Company and David Van Vliet complies with Fed. R. App. P. 32(a)(7)(B)(i) because it contains 13,557 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). I also certify that this brief complies with the typeface and style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared using Microsoft Word with a proportionally-spaced 14-point font in Times New Roman.

DATED: March 15, 2011

/s/ Robert P. Berry
Robert P. Berry

CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that on March 15, 2011, the foregoing Brief for Defendants-Appellees KV Pharmaceutical Company and David A. Van Vliet was filed with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit using the appellate CM/ECF filing system. The brief was scanned for viruses using Microsoft Forefront Client Security (updated March 15, 2011) and no viruses were detected.

DATED: March 15, 2011

/s/ Robert P. Berry
Robert P. Berry